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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,475	01/05/2006	Yuji Miyahara	HIRA.0214	6277

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,475	MIYAHARA ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/06, 11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This action is in response to papers filed 12 June 2008 in which the title and claim 12 were amended and claim 11 was canceled. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 12 December 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

The examiner for this application has changed. Please address future correspondence to Examiner BJ Forman, Art Unit,1634.

Claims 12-13 are under prosecution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 12-13 rejected under 35 U.S.C. 103(a) as being obvious over Miyahara (Miyahara, et al. US Patent Application Publication 20050170347, filed 12/19/01) in

view of Yazawa (Patent Application Publication Number 20040121354, patented 7/2/07, filed 5/27/03) and/or Nova et al (U.S. Patent No. 6,284,459, issued 4 September 2001).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Miyahara teaches in claim 4 "A method of analyzing nucleic acids comprising the steps of: (a) introducing a sample solution containing at least one kind of nucleic acid onto a substrate provided with a plurality of insulated gate field effect transistors on which each different kind of single stranded nucleic acid probe or branched nucleic acid probe is immobilized on the surface of gate insulators directly or via a carrier, and subjecting to hybridization with the single stranded nucleic acid probes or branched nucleic acid probes; (b) introducing a washing solution onto the substrate to remove unreacted nucleic acids from the surface of the substrate; (c) introducing an intercalator solution onto the substrate to react with formed double stranded nucleic acids; (d) introducing the washing solution onto the substrate to remove unreacted intercalator

from the surface of the substrate; and (e) introducing a buffer onto the substrate to measure outputs of the insulated gate field effect transistors."

Miyahara does not teach (from claim 12) that the FET has a transmission/reception antenna, a reception circuit, a transmission circuit and an external control unit (from claim 13) and that the FET has memory circuit.

However, Yazawa teaches a similar method of detecting biological material (col 3, lines 35-36) wherein DNA probes are fixed to a measurement apparatus and the coupling of target to probe is detected using a Field Effect Transistor (FET, col 4, lines 46-56) wherein the FET has an external control unit and antenna (col 4, lines 62-65) and specifically teaches that insulting film is controlled so that the magnetic field from the antenna can escape (Column 19, lines 27-31), thereby teaching the antenna is covered by (or embedded in) the insulating film, through which the magnetic field travels.

Yazawa teaches that the measurement apparatus comprises function blocks including a sensor, antenna, detection circuit (i.e. a reception circuit), rectifying circuit (i.e. a transmission circuit) and a communication circuit (col 9, lines 31-35).

Yazawa teaches that by integrating these function blocks on one chip, a small-sized lightweight measurement apparatus can be implemented while the process and assembly costs are minimized (col 9, lines 35-40). Yazawa teaches storing identification information (col 17, 54-56), and mounting memory for storing the sensor information (col 18, lines15-22).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Miyahara with the method of Yazawa that includes an external control unit and a FET containing an antenna, detection circuit, rectifying circuit and communication circuit because by integrating these function blocks on one chip, a small-sized lightweight measurement apparatus can be implemented while the process and assembly costs are minimized. Further it would have been prima facie obvious to add memory in order to store the sensor information.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the method of Miyahara with the method of Yazawa that includes using a FET containing an antenna, detection circuit, rectifying circuit and communication circuit because by integrating these function blocks on one chip, a small-sized lightweight measurement apparatus can be implemented while the process and assembly costs are minimized. Further the ordinary artisan would have been motivated to add memory in order to store the sensor information.

Furthermore, Nova et al teach a similar method of detecting biological material comprising a plurality of biomolecule detecting elements wherein DNA probes are fixed to a measurement apparatus and the coupling of target to probe is detected (Abstract, Column 15, lines 12-18, Column 76, lines 30-62) wherein the device has a control unit (#120) and antenna (#110) embedded within a polymer shell (#90)Column 52, line 33-67 and Fig. 5) wherein the measurement apparatus comprises a memory circuit for information storage, wherein a signal from the device includes an output value of a

transistor (Column 55-62) and wherein the device is useful for a variety of multiplex assays (Column 80, line 57-Column 82, line 16). Nova et al further teaches that the protective shell assures the integrity of the device components (Column 52, lines 43-51). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the embedded antenna of Nova to the device and methods of Mihara and Yazawa. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the added benefit of assuring the integrity of the device components as desired in the art (Nova, Column 52, lines 43-51).

2. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritz (Fritz, et al. PNAS October 29, 2002; 99(22): 14142-14146) in view of Hashimoto (Hashimoto, US Patent Number 5776672, patented 7/7/1998) in view of Nova et al (U.S. Patent No. 6,284,459, issued 4 September 2001).

3. Fritz teaches using field-effect sensors that are EIS (electrolyte-insulator-silicon) capacitors microfabricated at the termini of silicon cantilevers (i.e. insulated gate Field Effect Transistor). Fritz teaches in figure 3 the field effect detection of DNA hybridization. Fritz teaches the surface potential response from sensor 1 functionalized (i.e. immobilized) with probe oligonucleotide A and sensor 2 functionalized with probe oligonucleotide B. Fritz teaches injecting buffer, probe B, buffer, target oligo cA, buffer,

target oligo cB and buffer (page 14144, figure 3A and caption). (Note that for purposes of this rejection, the buffer is considered to be broadly encompassed by the buffer and wash solutions in the claims.) By detecting the changes in surface potential, Fritz teaches measuring output values.

While Fritz does teach a plurality of biomolecule detecting elements (A and B) hybridizing nucleic acids to probes and buffer solution in the reaction vessel, and detecting a signal, Fritz does not teach from claim 12: a transmission/reception antenna, reception circuit; a transmission circuit; or introducing an intercalator solution; and from claim 13: wherein the biomolecule detecting element comprises a memory circuit for storing identification information.

Hashimoto teaches a nucleic acid probe that is immobilized onto a carrier sensitive to a physical change, such as an electrode, ISFET, MOSFET (col 8, lines 36-42). Hashimoto teaches that the nucleic acid probe is used to hybridize to a complementary gene in order to detect the presence of the gene in a sample (col 2, lines 30-36). Hashimoto teaches intercalating agents that exhibit electrode response (col 3, lines 66-67 to col 4, lines 1-4), and Hashimoto teaches that intercalating agents that intercalate specifically to double stranded nucleic acid such as double stranded DNA (col 4, lines 5-15). Therefore, the intercalating agent is used to detect the binding of the probe to the gene (col 4, lines 66-67).

Furthermore, Nova et al teach a similar method of detecting biological material comprising a plurality of biomolecule detecting elements wherein DNA probes are fixed to a measurement apparatus and the coupling of target to probe is detected (Abstract,

Column 15, lines 12-18, Column 76, lines 30-62) wherein the device has a control unit (#120) and antenna (#110) embedded within a polymer shell (#90)Column 52, line 33-67 and Fig. 5) wherein the measurement apparatus comprises a memory circuit for information storage, wherein a signal from the device includes an output value of a transistor (Column 55-62) and wherein the device is useful for a variety of multiplex assays (Column 80, line 57-Column 82, line 16). Nova et al further teaches that the protective shell assures the integrity of the device components (Column 52, lines 43-51). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the embedded antenna of Nova to the device and methods of Fritz and Hashimoto. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the added benefit of assuring the integrity of the device components as desired in the art (Nova, Column 52, lines 43-51).

Furthermore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Fritz by using an intercalator in order to detect the presence of a gene by hybridizing the gene to a probe on a MOSFET or ISFET (types of field effect transistors) as described by Hashimoto.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the method of Fritz by using an intercalator, in order to detect the presence of a gene by hybridizing the gene to a probe on a MOSFET or ISFET (types of field effect transistors) as described by Hashimoto. The ordinary artisan would also have been motivated to modify the method of Fritz in view of Hashimoto by using

the apparatus of Nova in order to store various data, parameters and algorithms associated with event detection and identification.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 12-13 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-5 of copending Application No. 10/499,005 in view of Nova et al (U.S. Patent No. 6,284,459, issued 4 September 2001).

6. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of analyzing nucleic

acids comprising similar method steps, but differ in that the '005 claims are not drawn to a transmission/reception antenna, reception circuit; a transmission circuit; or the biomolecule detecting element comprises a memory circuit for storing identification information.

Nova et al teach a similar method of detecting biological material comprising a plurality of biomolecule detecting elements wherein DNA probes are fixed to a measurement apparatus and the coupling of target to probe is detected (Abstract, Column 15, lines 12-18, Column 76, lines 30-62) wherein the device has a control unit (#120) and antenna (#110) embedded within a polymer shell (#90)Column 52, line 33-67 and Fig. 5) wherein the measurement apparatus comprises a memory circuit for information storage, wherein a signal from the device includes an output value of a transistor (Column 55-62) and wherein the device is useful for a variety of multiplex assays (Column 80, line 57-Column 82, line 16). Nova et al further teaches that the protective shell assures the integrity of the device components (Column 52, lines 43-51). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the embedded antenna and circuit of Nova to the device '005 methods. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the added benefit of assuring the integrity of the detection device components as desired in the art (Nova, Column 52, lines 43-51).

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

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